# UNITED STATES DISTRICT COURT
# WESTERN DISTRICT OF TEXAS
# AUSTIN DIVISION

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| **LINDA ISAAC,** *Plaintiff* | § | |
| **v.** | § | **Case No. A-19-CV-895-LY** |
| **C. R. BARD, INC. and BARD PERIPEHERAL VASCULAR, INC.,** *Defendants* | § | |

## REPORT AND RECOMMENDATION OF THE UNITED STATES MAGISTRATE JUDGE

**TO: THE HONORABLE LEE YEAKEL**
**UNITED STATES DISTRICT JUDGE**

Before the Court are Defendants' Motion for Summary Judgment, filed January 8, 2021 (Dkt. 28); Plaintiff's Response to Defendants' Motion for Summary Judgment, filed January 25, 2021 (Dkt. 34); and Defendants' Reply in Support of Their Motion for Summary Judgment, filed February 5, 2021 (Dkt. 35). The District Court referred all motions in this case to the undersigned Magistrate Judge for resolution or Report and Recommendation, pursuant to 28 U.S.C. § 636(b)(1), Federal Rule of Civil Procedure 72, and Rule 1 of Appendix C of the Local Rules of the United States District Court for the Western District of Texas.

## I. Background

### A. Underlying MDL

This product liability case is one of more than 8,000 lawsuits filed in a multidistrict litigation proceeding ("MDL") against Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard manufactures and markets medical devices, including inferior vena cava ("IVC") filters.

The IVC is a large vein that returns blood to the heart from the lower body. An IVC filter is a small device implanted in the IVC to catch blood clots before they reach the heart and lungs. The MDL involved multiple versions of Bard's retrievable IVC filters, including the Recovery, G2, G2X, Eclipse, Meridian, and Denali. Each of these filters is a variation of its predecessor. These filters are umbrella-shaped devices that have multiple limbs fanning out from a cone-shaped head. The limbs consist of legs with hooks that attach to the IVC wall and curved arms to catch or break up blood clots.

The MDL Plaintiffs received implants of Bard's IVC filters, which Plaintiffs claim are defective and have caused them to suffer serious injury or death. The MDL Plaintiffs allege that Bard's IVC filters are more dangerous than other IVC filters because they have higher risks of tilting, fracturing, perforating the IVC, and migrating to vital organs. Plaintiffs further allege that Bard failed to warn patients and physicians about these higher risks. Defendants dispute these allegations, contending that Bard filters are safe and effective, that their complication rates are low and comparable to those of other IVC filters, and that the medical community is aware of the risks associated with IVC filters.

The MDL was formed to centralize all pretrial proceedings and complete all common fact and expert discovery concerning Bard's IVC filters. In August 2015, the Judicial Panel on Multidistrict Litigation assigned the MDL to the Honorable David G. Campbell, Senior United States District Judge for the U.S. District Court for the District of Arizona, in order to centralize all pretrial proceedings. Dkt. 3 at 1, 9. After all common fact and expert discovery concerning the Bard IVC filters was completed, Judge Campbell transferred each pending direct-filed case to the district identified in the short form complaint, pursuant to 28 U.S.C. § 1404(a). This case was transferred to the Western District of Texas on September 12, 2019. Dkt. 5.

**B. Plaintiff's Claims**

In March 2008, Plaintiff Linda Isaac was in a serious automobile accident and suffered significant bodily injuries. Plaintiff was in a coma for approximately three weeks and developed a pulmonary embolism in her lungs. Plaintiff's treating physician decided to surgically implant a Bard G2 IVC Filter ("G2 Filter") in Plaintiff "as prophylaxis against further pulmonary emboli." Dkt. 34 at 1. Plaintiff alleges that after the G2 Filter was implanted, she began to experience a cascade of "filter failures," including tilt, migration, fracture, and component embolization. *Id.* at 2. As a result, Plaintiff alleges, she suffered perforation of her IVC, penetration of lumbar vertebrae, embedding of the apex of the filter in the wall of her IVC, the embolization of pieces of the filter to the right ventricle of the heart and to her lung, and migration or penetration of filter fragments into her retroperitoneum and the area near her IVC. *Id.* at 2-4. Plaintiff alleges that these injuries have caused her to suffer pain in her back, abdomen, and chest, as well as fear of a potentially fatal movement of the filter fragment in her heart. Plaintiff contends that she needs to have the filter and the strut in her heart and lung removed, but that "removals will require open surgeries and advanced interventional radiology techniques that Ms. Isaac's local treating physicians were reluctant to undertake." *Id.* at 4.

Plaintiff alleges that Bard had known for years before her surgery that its G2 Filter had risks of tilt, fracture, migration, perforation, and embolization of components exceeding the risks associated with other available IVC filters. Plaintiff further alleges that Bard failed to comply with industry standards in designing the G2 Filter and failed to design the filter in a way that would reduce the risks of tilt, perforation, migration, and fracture by fatigue. Plaintiff contends that: "Had a reasonable physician been aware of these safety issues that were known to Bard at the time of Ms. Isaac's implant in March 2008, he or she would not have used the G2 Filter for prevention of pulmonary embolism in patients." *Id.* at 3. Plaintiff further avers that the Instructions for Use

provided with each G2 Filter failed to warn of significant information that Bard understood physicians and patients would want to know about the G2 Filter, notably its increased risk of adverse events, including tilt, perforation, migration, and fracture, in comparison to Bard's Simon Nitinol Filter and competitor filters. Plaintiff further contends that the Instructions for Use also promoted the G2 Filter as safe for permanent implantation, without giving any clear recommendations for imaging follow-up or a timeline for removal of the device.

In her Complaint, Plaintiff alleges manufacturing defect; design defect; failure to warn; negligent design; negligent manufacture; negligent failure to warn; negligence *per se*; breach of express warranty; breach of implied warranty; fraudulent misrepresentation; fraudulent concealment; and punitive damages.

Bard moves for summary judgment under Federal Rule of Civil Procedure 56(a) on all of Plaintiff's claims. In response, Plaintiff has withdrawn her clams for negligence per se, breach of express and implied warranty, and fraudulent concealment, but opposes the motion as to all other claims. Dkt. 34 at 1 n.1. The Court makes the following recommendations as to Plaintiff's remaining claims.

## II. Legal Standards

Summary judgment shall be rendered when the pleadings, the discovery and disclosure materials, and any affidavits on file show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-25 (1986); *Washburn v. Harvey*, 504 F.3d 505, 508 (5th Cir. 2007). A dispute regarding a material fact is "genuine" if the evidence is such that a reasonable jury could return a verdict in favor of the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). When ruling on a motion for summary judgment, the court is required to view all inferences drawn from the factual record in the light most favorable to the nonmoving

party. *Matsushita Elec. Indus. Co. v. Zenith Radio*, 475 U.S. 574, 587 (1986); *Washburn*, 504 F.3d at 508. A court "may not make credibility determinations or weigh the evidence" in ruling on a motion for summary judgment. *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000); *see also Anderson*, 477 U.S. at 254-55.

Once the moving party has made an initial showing that there is no evidence to support the nonmoving party's case, the party opposing the motion must come forward with competent summary judgment evidence of the existence of a genuine fact issue. *Matsushita*, 475 U.S. at 586. Mere conclusory allegations are not competent summary judgment evidence, and thus are insufficient to defeat a motion for summary judgment. *Turner v. Baylor Richardson Med. Ctr.*, 476 F.3d 337, 343 (5th Cir. 2007). Unsubstantiated assertions, improbable inferences, and unsupported speculation are not competent summary judgment evidence. *Id.* The party opposing summary judgment is required to identify specific evidence in the record and to articulate the precise manner in which that evidence supports its claim. *See Adams v. Travelers Indem. Co. of Conn.*, 465 F.3d 156, 164 (5th Cir. 2006). If the nonmoving party fails to make a showing sufficient to establish the existence of an element essential to its case and on which it will bear the burden of proof at trial, summary judgment must be granted. *Celotex*, 477 U.S. at 322-23.

## III. Analysis

Plaintiff's remaining claims allege manufacturing defect; design defect; failure to warn; negligent design; negligent manufacture; negligent failure to warn; fraudulent misrepresentation; and punitive damages. Bard argues that it is entitled to summary judgment on all of Plaintiff's claims because Plaintiff has failed to establish a genuine issue of material fact regarding causation. Alternatively, Bard argues that Plaintiff's claims should be dismissed for failure to state a claim as a matter of law. The parties agree that Texas law applies to this case.

**A. Causation**

Under Texas law, all of Plaintiff's claims require proof of causation. *See Meador v. Apple, Inc.*, 911 F.3d 260, 264 (5th Cir. 2018) ("Negligence and products liability claims both require proof of causation."), *cert. denied,* 139 S. Ct. 2649 (2019); *Horak v. Pullman, Inc.*, 764 F.2d 1092, 1095 (5th Cir. 1985) (concluding that Texas law requires proof of causation for product liability claims based on negligence and strict liability theories); *Hyundai Motor Co. v. Rodriguez ex rel. Rodriguez*, 995 S.W.2d 661, 667 (Tex. 1999) ("Liability for breach of warranty requires a showing of proximate cause."). Thus, Plaintiff must show that the G2 Filter "was a producing cause of the injury for which the plaintiff seeks recovery." *Timpte Indus., Inc. v. Gish*, 286 S.W.3d 306, 311 (Tex. 2009). "A producing cause must be a cause-in-fact; that is, it must be a substantial factor in bringing about the injury, and a cause without which the injury would not have happened." *BIC Pen Corp. v. Carter*, 346 S.W.3d 533, 541 (Tex. 2011); *see also Meador*, 911 F.3d at 265 ("Causation for both negligence and products liability therefore turns on whether an alleged cause of an injury may be recognized as a 'substantial factor.'"). The general rule long has been that expert testimony is necessary to establish causation as to medical conditions outside the common knowledge and experience of jurors. *Guevara v. Ferrer*, 247 S.W.3d 662, 665 (Tex. 2007); *see also Anderson v. Siemens Corp.*, 335 F.3d 466, 474 (5th Cir. 2003) ("Ordinarily, expert testimony is needed to satisfy the reasonable medical probability standard for establishing a causal link.").

Plaintiff has designated Dr. Darren Hurst, a vascular and interventional radiologist, as her expert witness to testify as to medical causation and specifically that the G2 Filter caused Plaintiff's injuries. Bard argues that Plaintiff has failed to meet her burden to show that the G2 Filter is the proximate cause of her alleged injuries because Dr. Hurst failed to testify at deposition that Plaintiff's back and abdominal pain "were caused by the condition of her Filter or whether

they were caused by her significant injuries she incurred in the automobile accident." Dkt. 28 at 5.[1] Bard relies on the following exchange between Dr. Hurst and defense counsel:

> Q. And you don't take into consideration the significant back injuries and abdominal injuries that she suffered from the 2008 motor vehicle accident, which she describes as life[-]changing, correct?
>
> A. She has back pain and abdominal pain, both of which could have been caused by her prior MVA and by the filter, both.
>
> Q. And within a reasonable degree of medical certainty, can you distinguish or quantify what percentage of [Plaintiff's] chronic back pain [and chronic abdominal pain] is a result of the significant injuries from the motor vehicle accident or from the condition of her IVC filter?
>
> A. You can't until you remove the device.

Hurst Dep. at 83:4-22, Dkt. 33-2 at 516 (objections omitted).[2] Bard contends that Dr. Hurst's answer demonstrates that Plaintiff cannot meet her burden to show that the G2 Filter is the proximate cause of her alleged injuries.

The Court is not persuaded. First, Bard fails to acknowledge that there can be more than one proximate cause of an injury. *Stanfield v. Neubaum*, 494 S.W.3d 90, 97 (Tex. 2016). In addition, Bard ignores the rest of Dr. Hurst's deposition testimony and his Expert Report, in which Dr. Hurst opines that the G2 Filter was the proximate cause of Plaintiff's injuries. For example, immediately before defense counsel asked Dr. Hurst to quantify what percentage of Plaintiff's pain was caused by the G2 Filter or the automobile accident, Dr. Hurst testified that the "likely cause" of Plaintiff's chronic back and abdominal pain was the GT Filter. Hurst Dep. at 82:24-83:7, Dkt. 33-2 at 516. Dr. Hurst further testified that that he did not agree that Plaintiff's back pain and abdominal pain predated perforation by the G2 Filter: "I don't agree. The IVC filter perforated the moment it was placed." *Id.* In addition, Dr. Hurst opines in his Expert Report that:

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[1] Judge Campbell denied Bard's *Daubert* Motion to Strike Dr. Hurst in the underlying MDL. Dkt. 3 at 20.

[2] The Court refers to evidence in the record by the docket and page numbers in CM/ECF.

- The plaintiff's G2 filter failed to perform as a reasonable physician and/or patient would expect in that the filter penetrated the IVC with interaction with or penetration of the lumbar spine, duodenum, psoas muscle, and the retroperitoneum. These penetrations are the likely cause of the plaintiff's chronic low back pain and chronic abdominal pain.
- In my opinion, within reasonable medical certainty, the failure of the plaintiff's filter, which caused two fractured, embolized components of the filter to migrate as described above, has put her at an increased risk of future complications. The fragments would require open surgical procedures to remove if complications occur. These procedures have a high risk of complications, including significant morbidity and the risk of death.
- In rendering my opinions in this matter, I took into consideration the plaintiff's co-morbidities, medical history, and preexisting problems, and ruled these out as the cause of her filter's failure.
- All of my opinions are to a reasonable degree of medical and scientific certainty.

Hurst Expert Report, Dkt. 33-2 at 540-42.

The Court finds that Dr. Hurst's deposition testimony and opinions expressed in his Expert Report are sufficient to create a material fact issue as to whether the G2 Filter caused Plaintiff's injuries. In addition, Bard's challenges to Dr. Hurst's opinions turn on fact issues for the jury and are more properly the subject of cross-examination at trial. Accordingly, the Court finds that Bard is not entitled to summary judgment for failure to create a fact issue as to causation.

**B. Future Damages and Medical Expenses**

Alternatively, Bard argues that it is entitled to summary judgment on Plaintiff's claims for future damages and medical expenses because Dr. Hurst's opinions fail to demonstrate within a medical degree of certainty that Plaintiff will need future medical treatment. As noted above, Dr. Hurst's Expert Report states that, "within reasonable medical certainty, the failure of the plaintiff's filter, which caused two fractured, embolized components of the filter to migrate as described above, has put her at an increased risk of future complications," which will require future

"open surgical procedures to remove if complications occur." Dkt. 33-2 at 540-42. The Court finds that Dr. Hurst's testimony and opinions expressed in his Expert Report are sufficient to create a material fact issue as to Plaintiff's future damages and medical expenses. Again, Bard's challenges to Dr. Hurst's opinions turn on fact issues for the jury and are more properly the subject of cross-examination at trial. Accordingly, Bard is not entitled to summary judgment as to these claims.

**C. Warning-Based Claims**

Bard next argues that Plaintiff's failure to warn, negligent failure to warn, and fraudulent misrepresentation claims fail under the learned-intermediary doctrine. Under the learned-intermediary doctrine, the manufacturer in a medical products liability action "satisfies its duty to warn the end user of its product's potential risks by providing an adequate warning to a 'learned intermediary,' who then assumes the duty to pass on the necessary warnings to the end user." *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753, 774 (5th Cir. 2018) (quoting *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 142 (Tex. 2012)). Where the learned-intermediary doctrine applies, "plaintiffs must show that, but for the inadequate warning, their doctors would have recommended different treatment, or provided additional warnings that would have led plaintiffs to withhold consent." *Id.* (citations omitted). The Fifth Circuit has explained that causation in the context of the learned-intermediary doctrine entails two distinct factual predicates: (1) that the doctor would have read or encountered the adequate warning, and (2) that the adequate warning would have altered his treatment decision for, or risk-related disclosures to, the patient. *Id.* at 775.

Bard argues that it is entitled to summary judgment on Plaintiff's failure to warn claims because Plaintiff failed to depose the implanting physician and, therefore, there is no evidence regarding the implanting physician's impressions of the warnings, or whether any alternative warning would have caused him to use a different product to treat Plaintiff. Plaintiff admits that

she has been "unsuccessful" in obtaining her implanting physician's deposition or written statement in this case, but contends that she has produced sufficient evidence from her causation expert to raise a fact issue as to whether Bard's inadequate warnings were a producing cause of her injuries. Specifically, Plaintiff argues that Dr. Hurst's statement that "a reasonable implanting physician, if made aware of the safety issues known to Bard at the time the G2 Filter was implanted into Ms. Isaac in 2008, would not have used the G2 filter for the prevention of pulmonary embolism in patients" is sufficient to raise a fact issue as to whether Bard's inadequate warnings were a producing cause of Ms. Isaac's injuries. Dkt. 34 at 10. However, the learned-intermediary analysis focuses on the actions of the treating physician, not the opinion of an expert witness.

As noted, to overcome summary judgment, Plaintiff must produce evidence showing that (1) her implanting physician would have read or encountered the adequate warning, and (2) the adequate warning would have altered her physician's treatment decision for Plaintiff. *Pinnacle Hip Implant*, 888 F.3d at 775. In *Pinnacle Hip Implant*, the Fifth Circuit recognized that "objective evidence" may be "relevant" to the second part of this test, but not the first. *Id.* at 774-75 & n.30. Furthermore, the court noted that it had rejected at summary judgment a failure to warn claim where the treating physician "did not recall ever reading the package insert" and plaintiff offered no more than "speculation" about other ways an adequate warning might have reached the treating physician and altered her decision. *Id.* at 775 n.27 (quoting *Pustejovsky v. Pliva Inc.*, 623 F.3d 271, 277 (5th Cir. 2010)). Ultimately, the Fifth Circuit struck down the jury's failure to warn verdict for two of the plaintiffs, holding that the claims failed because the plaintiffs' treating doctors "did not testify, and plaintiffs offer[ed] no record evidence suggesting the two [doctors] actually read or encountered defendants' inadequate warnings." *Id.* at 775; *see also Centocor*, 372 S.W.3d at 171 (finding that plaintiffs presented no evidence that their prescribing physicians would have

acted differently had defendant provided a different warning); *Wessels v. Biomet Orthopedics, LLC*, No. 18-CV-97-KEM, 2020 WL 3421478, at *15 (N.D. Iowa June 22, 2020) (granting summary judgment on plaintiff's failure to warn claim where plaintiff presented no subjective evidence establishing how additional warnings might have reached her doctor and altered his decision).

Here, too, Plaintiff offers no evidence that her implanting physician would have read or encountered the adequate warning, and that the adequate warning would have altered her physician's treatment decision for Plaintiff. *Pinnacle Hip Implant*, 888 F.3d at 775. Absent this evidence, "any inadequacy [in] the product's warning, as a matter of law, is not the producing cause of the patient's injuries." *Id.* at 774 Accordingly, Bard is entitled to summary judgment on Plaintiff's failure to warn claims, including Plaintiff's failure to warn, negligent failure to warn, and fraudulent misrepresentation claims. *See Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767, 773 (S.D. Tex. 2008) ("Where the crux of the suit is based on a failure to adequately warn, the learned intermediary doctrine may apply to strict liability, negligence, misrepresentation, and breach of warranty claims."), *aff'd*, 321 F. App'x 350 (5th Cir. 2009).

**D. Design Defect**

To establish a design defect, Plaintiff has to prove that "(1) the product was defectively designed so as to render it unreasonably dangerous; (2) a safer alternative design existed; and (3) the defect was a producing cause of the injury for which the plaintiff seeks recovery." *Pinnacle Hip Implant*, 888 F.3d at 765. A safer alternative design is one that "would have prevented or significantly reduced the risk of the claimant's personal injury without substantially impairing the product's utility." *Id.* A plaintiff "must show the safety benefits from the proposed design are foreseeably greater than the resulting costs, including any diminished usefulness or diminished

safety." *Id.* at 765-66. In addition, a "substantially different product" cannot constitute a safer alternative design. *Id.* at 766.

Bard argues that it is entitled to summary judgment on Plaintiff's design defect claim because it is foreclosed by Comment k to Restatement (Second) of Torts § 402A, which provides:

> *Unavoidably unsafe products*. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like . . . .

Restatement (Second) of Torts § 402A, cmt. k (Am. Law. Inst. 1965). Bard argues that the G2 Filter is unavoidably unsafe because it carries the risk of death, recurrent pulmonary embolism, IVC occlusion, filter embolization, IVC perforation, migration, filter fracture, and other complications. Thus, Bard contends, Plaintiff' strict liability design defect claim is converted into a negligent failure to warn claim, which is precluded under Comment k.

Bard's argument is foreclosed by Fifth Circuit precedent. In *Pinnacle Hip Implant*, the Fifth Circuit explained that while the Texas Supreme Court has incorporated § 402A into its common law and has considered Comment k in the prescription drug context, "it has never expressly extended the immunity rule to medical implants, let alone 510(k)-cleared devices, on either a categorical or a product-by-product basis." 888 F.3d at 772. The Court further held that the blanket immunity under Comment k does not apply to medical implants, and, therefore, Comment k did not bar the plaintiff's design defect claim. *Id.* Accordingly, Bard's argument that Plaintiff's design defect claim is precluded under Comment k is without merit.

Alternatively, Bard argues that it is entitled to summary judgment on Plaintiff's design defect claim because Plaintiff cannot prove that a safer alternative design existed. As noted, Plaintiff bears the burden to show that a safer alternative design existed. *Id.* at 765. The alternative device cannot be a "substantially different product." *Id.* at 766. Bard contends that permanent IVC filters are substantially different products than retrievable IVC filters like the G2 Filter. Because Plaintiff has identified only permanent filters (such as the Simon Nitinol Filter) as alternative designs to the retrievable G2 Filter, Bard argues, she has failed to show that an alternative design of a similar product existed.

The Court finds that there is a material fact issue as to whether the Simon Nitinol Filter is a "substantially different product" than the G2 Filter. Bard marketed the G2 Filter as a permanent filter with the option of retrieval. *See* Instructions for Use, Dkt. 28-1 at 76 ("The G2 Filter is designed to act as a permanent filter. When clinically indicated, the G2 Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure."). In addition, the FDA approved the G2 Filter as "indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava." FDA Approval Letter, Dkt. 28-1 at 91. Finally, Judge Campbell ruled in the MDL that the jury should be allowed to determine whether the Simon Nitinol Filter is a safer device than the G2 Filter. *In re Bard IVC Filters Prod. Liab. Litig.*, No. MDL 15-02641-PHX DGC, 2018 WL 775296, at *6 (D. Ariz. Feb. 8, 2018) ("The Court will not grant Defendants' request to preclude Dr. McMeeking from opining that the SNF is a safer device than Bard retrievable filters."). Therefore, the Court finds that there are material fact issues precluding summary judgment on Plaintiff's design defect claim.

**E. Negligent Manufacturing**

Bard first argues that Plaintiff's negligent manufacturing claim fails for the same reason as the design defect claim, that is, that Plaintiff cannot prove a reasonable alternative design. As stated above, the Court rejects this argument.

Alternatively, Bard argues that it is entitled to summary judgment because Plaintiff has failed to produce evidence that the G2 Filter deviated from its design specifications or planned output. Plaintiff, however, submitted evidence supporting her claim that the G2 Filter differed from both its specifications and planned output in a manner that rendered it unreasonably dangerous. Plaintiff has provided evidence that the basic performance specifications for the G2 Filter were that the device "must not" migrate, perforate the blood vessel, or break or come apart during their lifetime, and must not fracture as result of corrosion or stresses within the body. Dkt. 33-1 at 54-59. Plaintiff alleges that her G2 Filter failed to comply with all of these specifications within weeks after it was implanted. Plaintiff relies on the expert testimony of Dr. Hurst to support her allegations. Dkt. 33-2 at 516, 540-42. The Court finds that Plaintiff has alleged sufficient facts to raise a material fact issue as to her negligent manufacturing claim.

**F. Texas Civil Practices and Remedies Code § 82.008**

Bard argues that two provisions of the Compliance with Government Standards contained in § 82.008 of the Texas Civil Practices and Remedies Code ("TCPRC") establishes "independent rebuttable presumptions of non-liability as to all of Plaintiff's claims." Dkt. 28 at 14.

**1. Section 82.008(c)**

Section 82.008(c) of the TCPRC provides that in a products liability action brought against a manufacturer, a "rebuttable presumption" arises that the manufacturer is not liable for any injury to a plaintiff allegedly caused by an aspect of the formulation, labeling, or design of a product if:

> (1) the product manufacturer or seller establishes that the product was subject to pre-market licensing or approval by the federal government, or an agency of the federal government;
>
> (2) the manufacturer complied with all of the government's or agency's procedures and requirements with respect to pre-market licensing or approval; and
>
> (3) after full consideration of the product's risks and benefits the product was approved or licensed for sale by the government or agency.[3]

In order to market and sell the G2 Filter, Bard went through the FDA's 510(k) clearance process. *See* 21 C.F.R. §§ 807.87, 807.92, 807.93 (2021) (describing the requirements for 510(k) clearance). The 510(k) clearance process "imposes a limited form of review" on manufacturers of qualifying devices. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996). "If the FDA concludes on the basis of the § 510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis." *Id.* On August 29, 2006, the FDA notified Bard that the G2 Filter "is substantially equivalent" to pre-existing devices and can be marketed "subject to the general controls provisions of the Act and the limitations described below." Dkt. 28-1 at 86 (the "510(k) Letter"). However, the 510(k) Letter also stated that Bard must include the following "limitation" in the precautions section of the G2's labeling and in promotional materials: "The safety and effectiveness of the G2 Filter System for use as a retrievable or temporary filter have not been established." *Id.*

Bard contends that because the G2 Filter was "cleared for sale by the FDA following Bard's successful '510(k)' application to the FDA," the rebuttable presumption contained in § 82.008(c)

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[3] The plaintiff may rebut this presumption by establishing that:

> (1) the standards or procedures used in the particular pre-market approval or licensing process were inadequate to protect the public from unreasonable risks of injury or damage; or
>
> (2) the manufacturer, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the government or agency information that was material and relevant to the performance of the product and was causally related to the claimant's injury.

TEX. CIV. PRAC. & REM. CODE ANN. § 82.008(c).

precludes all of Plaintiff's claims. Dkt. 28 at 15. Bard's reliance on the 510(k) process to argue that the G2 Filter was subject "to pre-market licensing or approval" is misplaced. TEX. CIV. PRAC. & REM. CODE ANN. § 82.008(c). The FDA's clearance of a device under the 510(k) process is not the same as a pre-market approval of a device under the FDA's pre-market approval ("PMA") process. *See Pinnacle Hip Implant*, 888 F.3d at 770 (stating that the 510(k) process does not "denote official approval of the device"); *Horn v. Thoratec Corp.*, 376 F.3d 163, 167 (3d Cir. 2004) ("A device found to be 'substantially equivalent' to a predicate device is said to be 'cleared' by FDA (as opposed to 'approved' by the agency under a PMA)."). As the Supreme Court has explained:

> The § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours. As one commentator noted: The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly.

*Lohr*, 518 U.S. at 478-79 (cleaned up). In addition, the 510(k) process focuses on "*equivalence*, not safety." *Id.* at 493. As a result, "substantial equivalence determinations provide little protection to the public." *Id.* Because the FDA makes no determination regarding the device's safety and effectiveness in the § 510(k) approval process, FDA regulations specifically prohibit a manufacturer from "misbranding" a 510(k)-cleared device by claiming that it has been "approved" by the FDA. *In re Bard IVC Filters*, No. MDL 15-02641-PHX DGC, 2017 WL 5625547, at *7 (D. Ariz. Nov. 22, 2017) (citing 21 C.F.R. § 807.97), *aff'd*, 969 F.3d 1067 (9th Cir. 2020).

Due to these differences between 510(k) and PMA processes, courts have held that "the 510(k) approval process, because of its lack of focus on safety, does not entitle a manufacturer to the rebuttable presumption established under Texas law for product liability defendants, in which a manufacturer that complies with governmental safety standards can be shielded from liability."

*Till v. X-Spine Sys., Inc.*, No. 3:15-CV-00532-M, 2015 WL 3903567, at *4 n.26 (N.D. Tex. June 24, 2015); *see also Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 761 (S.D. W. Va. 2014) (holding that § 510(k) approval process for surgical mesh devices did not confer rebuttable presumption established under TEX. CIV. PRAC. & REM. CODE § 82.008(c)). The Court finds that the rebuttable presumption in § 82.008(c) of the TCPRC does not apply here.

**2. Section 82.008(a)**

Bard also argues that the rebuttable presumption in § 82.008(a) precludes Plaintiff's claims. Section 82.008(a) of the TCPRC provides:

> In a products liability action brought against a product manufacturer or seller, there is a rebuttable presumption that the product manufacturer or seller is not liable for any injury to a claimant caused by some aspect of the formulation, labeling, or design of a product if the product manufacturer or seller establishes that the product's formula, labeling, or design complied with mandatory safety standards or regulations adopted and promulgated by the federal government, or an agency of the federal government, that were applicable to the product at the time of manufacture and that governed the product risk that allegedly caused harm.

Thus, in order for the rebuttable presumption to apply, Bard must establish that (1) the G2 Filter's formula, labeling, or design complied with mandatory safety standards or regulations adopted and promulgated by the federal government, which were (2) applicable to the product at the time of manufacture, and which (3) governed the G2 Filter's risk that allegedly caused Plaintiff's injuries.

Bard argues that § 82.008(a) applies here because the G2 Filter was subject to a 1999 FDA guidance document entitled "Guidance for Cardiovascular Intravascular Filter 510(k) Submissions," which contains the following statement:

> This guidance document describes a means by which cardiovascular intravascular filter devices may comply with the requirement of special controls for class II devices. Designation of this guidance document as a special control means that manufacturers attempting to establish that their device is substantially equivalent to a predicate cardiovascular intravascular filter device should demonstrate that

> the proposed device complies with either the specific recommendations of this guidance or some alternate control that provides equivalent assurances of safety and effectiveness.

Dkt. 28-1 at 136. Bard contends that: "The 510(k) submission for the Filter complied with this guidance document, as indicated by the FDA's clearance of the device." Dkt. 28 at 17. As discussed above, however, the § 510(k) clearance does not focus on the product's "safety or efficacy" *Lewis*, 991 F. Supp. 2d at 761, and there is nothing in the 510(k) Letter to indicate that the FDA applied the standards imposed in the FDA's Guidance Document. In fact, the 510(k) Letter specially states that the "FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act . . . ." Dkt. 28-1 at 87. In addition, Judge Campbell addressed the FDA's 1999 Guidance Document in the underlying MDL and rejected Bard's argument that it is a "specific and detailed directive the FDA issued for IVC filters." *In re Bard*, 2017 WL 5625547, at *8 ("The 1999 guidance document is not a 'directive' as Bard claims. . . . The document describes itself as a 'draft,' and makes clear that it does not mandate any particular course of action.").

Bard also argues that the G2 Filter was subject to the FDA's General Controls for Medical Devices, which "apply to all medical devices." Dkt. 28-1 at 146. Bard, however, has failed to demonstrate that the FDA specifically applied these general standards to the G2 Filter during the 510(k) process. In addition, Bard fails to point to any evidence showing that the general standards deal with the particular injuries alleged by Plaintiff. Accordingly, Bard fails to demonstrate that § 82.008(a) precludes Plaintiff's claims.[4]

[4] The Court need not address Bard's argument regarding the applicability of § 82.007(a) to Plaintiff's warning-based claims because the Court has determined that those claims should be dismissed.

**G. Punitive Damages**

Bard next argues that there is a conflict between Texas and Arizona law regarding punitive damages, and the Court should apply Arizona law to find that Plaintiff's claim for punitive damages is barred. Alternatively, Bard argues that Plaintiff's claim for punitive damages fails under Texas law because Plaintiff has not presented clear and convincing evidence of fraud, malice, or gross negligence.

A federal court exercising diversity jurisdiction must apply the choice of law rules of the forum state, in this case Texas. *Mayo v. Hartford Life Ins. Co.*, 354 F.3d 400, 403 (5th Cir. 2004). Texas uses the "most significant relationship" test from the Second Restatement of Conflicts to decide choice of law issues. *See id.*; *Torrington Co. v. Stutzman*, 46 S.W.3d 829, 848 (Tex. 2000); Restatement (Second) of Conflicts §§ 6, 145 (1971). In tort cases, the most significant relationship turns on several factors: (a) the place where the injury occurred; (b) the place where the conduct causing the injury occurred; (c) the domicile, residence, nationality, place of incorporation, and place of business of the parties; and (d) the place where the relationship, if any, between the parties is centered. Restatement (Second) of Conflicts § 145; *see also Gutierrez v. Collins*, 583 S.W.2d 312, 319 (Tex. 1979).

Considering these factors, the Court finds that Texas law applies to Plaintiff's claim for punitive damages. Plaintiff's alleged injuries occurred in Texas, her surgery took place in Texas, and she was a Texas resident at the time of her surgery and throughout this litigation. *See Marrufo v. Ethicon, Inc.*, No. DR-20-CV-00043-AM, 2020 WL 7680562, at *2 (W.D. Tex. Nov. 20, 2020) ("Because the Plaintiff's alleged injuries occurred in Texas, the surgery took place in Texas, and the Plaintiff was a resident of the state at the time of the surgery, and throughout litigation, the Court finds that Texas has the most significant relationship to this case. Texas substantive law will

apply."). Accordingly, the Court finds that Texas has the most significant relationship to this case and Texas substantive law should apply.

Under Texas law, a plaintiff is entitled to punitive damages on a showing of gross negligence. *Hansen v. Johns-Manville Prods. Corp.*, 734 F.2d 1036, 1040 (5th Cir. 1984). To prevail on her claim of gross negligence, Plaintiff must prove both an objective and subjective component of her claim: (1) that viewed objectively from the standpoint of Bard at the time of the events underlying this suit, the act or omission of Bard involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others; and (2) that Bard had actual, subjective awareness of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others. *See* TEX. CIV. PRAC. & REM. CODE § 41.001(11); *U-Haul Int'l, Inc. v. Waldrip*, 380 S.W.3d 118, 137 (Tex. 2012). Plaintiff must prove these elements by clear and convincing evidence. *Diamond Shamrock Ref. Co. v. Hall*, 168 S.W.3d 164, 166 (Tex. 2005). The "clear and convincing" burden "means the measure or degree of proof that will produce in the mind of the trier of fact a firm belief or conviction as to the truth of the allegations sought to be established." TEX. CIV. PRAC. & REM. CODE § 41.001(2).

In support of her claim that Bard acted with gross negligence, Plaintiff contends that the record "contains ample evidence from which a reasonable jury may conclude that Bard's management-level employees knew the G2 posed a substantially greater risk of failure, resulting in serious injury and death, than other IVC available on the market (including its own SNF)." Dkt. 34 at 23. For example, Plaintiff points to evidence in the record showing that although Bard had determined by March 2, 2006 that the G2 Filter's propensity for caudal migration represented an unacceptable risk of serious injury and death, it took no preventive action to warn physicians or patients about the unacceptable risk and continued to manufacture it and similar filters. Natalie Wong Dep. at

155:10-156:12, 179:9-13, 181:11-22, Dkt. 34-1 at 423-25, 427; Chad Modra Dep. at 22:12-26:13, 59:6-21, 64:6-69:24, 76:13-87:25, 89:14-94:9, Dkt. 33-2 at 180-94.

Plaintiff points to additional evidence showing that Bard became aware in 2008 and 2009 that the G2 Filter had significantly higher rates of caudal migration, tilt, perforation, and fracture than other IVC filters. Dkt. 33-1 at 696-713; Dkt. 33-2 at 53-62. Plaintiff also identifies deposition testimony from Christopher Ganser, Bard's Vice President of Quality Assurance, Regulatory Affairs and Medical Affairs, that Bard knew and should have communicated to physician and patients: (1) statistically significant findings that Bard's Recovery filters revealed increased risks and complications compared to the predicate device; (2) that tilting was a condition that could put a patient at an increased risk of perforations, migrations, fracture, and could adversely affect the device's ability to work for its intended purpose of stopping pulmonary embolisms; (3) that tilting could lead to further movement of its filters that results in embedment making it irretrievable via a percutaneous approach; and (4) its internal analysis concluding G2 products were experiencing undesirable risk of caudal migration. Ganser Dep., Dkt. 34-1 at 842-64.

The Court finds that Plaintiff has produced sufficient evidence to create a fact issue as to whether Bard acted with gross negligence. Accordingly, the Court recommends against summary judgment on Plaintiff's claim for punitive damages under Texas law.

## IV. Recommendation

Based on the foregoing, the undersigned **RECOMMENDS** Bard's Motion for Summary Judgment (Dkt. 28) is **GRANTED IN PART** and **DENIED IN PART**. The undersigned **RECOMMENDS** that the District Court **GRANT** the motion as to Plaintiff's failure to warn, negligent misrepresentation, and fraudulent misrepresentation claims, and **DENY** the motion as to Plaintiff's manufacturing defect, design defect, negligent design, negligent manufacture, future damages and medical expenses, and punitive damages claims.

## V. Warnings

The parties may file objections to this Report and Recommendation. A party filing objections must specifically identify those findings or recommendations to which objections are being made. The District Court need not consider frivolous, conclusive, or general objections. *See Battle v. United States Parole Comm'n*, 834 F.2d 419, 421 (5th Cir. 1987). A party's failure to file written objections to the proposed findings and recommendations contained in this Report within fourteen (14) days after the party is served with a copy of the Report shall bar that party from de novo review by the District Court of the proposed findings and recommendations in the Report and, except on grounds of plain error, shall bar the party from appellate review of unobjected-to proposed factual findings and legal conclusions accepted by the District Court. *See* 28 U.S.C. § 636(b)(1); *Thomas v. Arn*, 474 U.S. 140, 150-53 (1985); *Douglass v. United Servs. Auto. Ass'n*, 79 F.3d 1415, 1428-29 (5th Cir. 1996) (en banc).

**SIGNED** on March 29, 2021.

SUSAN HIGHTOWER
UNITED STATES MAGISTRATE JUDGE